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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/091,665	09/02/1998	JAN ENDRIKAT	SCH1637	5200

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EXAMINER	
QAZI, SABIHA NAIM	

ART UNIT	PAPER NUMBER
1616	27

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/091,665	ENDRIKAT ET AL.	
	Examiner	Art Unit	
	Sabiha N. Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *4-7,14-30 and 36-77* is/are pending in the application.

4a) Of the above claim(s) *36-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4-7 and 14-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *36-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Final Office Action

Acknowledgement is made of the response and amendments in paper no. 24 filed on 9/24/2003.

Claims 3-7, 14-30, 36-77 are pending. New claims 70-77 are added. No claim is allowed at the present time. Amendments are entered.

Arguments are found persuasive therefore, the 35 U.S.C. 112 rejection is withdrawn, others rejections are maintained for the same reasons as set forth in our previous office action.

Claims 3-7 and 14-30 are considered too broad and the specification(s) is not supported by example(s) or any data, claims stand rejected under 35 U.S.C. 112 first and second paragraphs, for the reasons cited below. In the steroid art especially in estrogen therapy and combinations with gestagen a small amount of the components or combination of different estrogen and gestagen lead to different results. Applicant is requested to see prior art of record. It is impossible to predict the contraception in such a wide range of combinations of gestagen and estrogens, durations and other limitations as claimed.

Case laws cited by applicants were fully considered but was not considered as persuasive to withdraw the rejection. Applicant is requested to see the most relevant case laws cited by the Examiner in first paragraph rejection.

It is suggested to narrow the claims to the invention supported by the disclosure. At this point, claims are not considered allowable.

Rejection under 35 U.S.C. 103(a) is maintained because the prior art teaches a method similar to presently claimed invention. It does not matter if the prior art uses a synthetic steroid because it teaches the same *method* as the presently claimed invention. The prior art does, in fact,

teach the exact combination and dosage schedule; it is actually the *presently claimed invention* that fails to provide any specifics. Request for consideration of examination of claims 36-56 is denied because the claims are not dependent on claim 14.

In order to have a clear view of the prosecution history for appeal and/or Examiner's Answer following review is considered necessary.

1. Claims 1-12 were originally filed. Now claims 4-7, 14-30, 36-77 are pending. Claims 14, 36, 37, 38 and 56 are independent claims.

2. New claims 13-30 were added and claims 1-7 are amended, (response filed on 6/29/2000).

3. New claims 31-35 were added, (response filed on 6/16/2001).

4. New claims 36-56 were added, (response filed on 9/25/2002).

5. A petition was filed on 7/12/01 and was later dismissed.

6. New claims 57-69 were added (response filed on 4/8/2003).

7. New claims 70-77 were added in the response filed on 9/24/03.

Claim Rejections - 35 USC § 112(1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7 and 14-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Two reasons why the Claims are rejected under the first paragraph of 35 U.S.C. 112:

1) Claim 14 does not have any specifics. The reference (WEINER et al) goes into detail about what days to use what, what specific compounds to use, how much to use them, etc.

2) Claim 4 is drawn to "the method according to claim 14, wherein the gestagen is gestodene, progesterone, levonorgestrel, cryptoterone acetate, chloromadinone acetate, drospirenone (dihydrospirorenone), norethisterone, norethisterone acetate, norgestimate, desogestrel, 3-ketodesogestrel, dienogest, or mixtures thereof." This claim is not specific enough because there are too many gestagen groups to choose from. One skilled in the art would not be able to tell the difference of the effects on a female mammal if one were to use progesterone, dienogest, or a mixture of drospirenone and chloromadinone acetate.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the

above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

***The nature of the invention*:** The invention is directed to methods of contraception in a mammal by administering gestagen and estrogen for at least 28 days wherein gestagen is given in the first phase.

The state of the prior art: Various combination of estrogen, gestagen by administering in different phases are known. See prior art of record where each combination and duration is critical for the treatment. Presently claimed gestagens and estrogens are not limited, and there is no data or showing for any combination. Furthermore, there is no description how every gestagen and estrogen combination would be useful.

***The predictability or lack thereof in the art*:** There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Therefore predicting which compounds within the broad genus will be useful is impossible.

***The presence or absence of working examples*:** There is no actual working example of any in vivo, or in vitro test data, which would assist the skilled artisan in practicing the claimed invention. The skilled artisan, seeking to use the invention, would be at a loss as to where to begin such discovery in the absence of such data.

***The breadth of the claims*:** The claims are broad see for example claim 14 where combination of any gestagen and estrogen is claimed when there is no example in the specification.

The amount of direction or guidance presented: The specification provides no guidance that for the claimed invention. See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)

(contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The quantity of experimentation needed: Since different aspects of biological activity cannot be predicted but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation study. Since the nature of the method is so unpredictable, and since the claims are drawn to a broad range of estrogens and gestagen combination and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Since the nature of the method is so unpredictable, and since the claims are drawn to a broad range of pharmaceuticals for treatment of such a broad range of disease states, and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Claims 3-7 and 14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al. (DN 86:12188, CAPLUS, abstract of Contraception (1976), 14(5), 551-62). The reference teaches a combination of gestagen and estrogen, which embraces presently claimed invention. See the abstract. The reference teaches the application of gestagen in the first phase, than after about 300 days of treatment with gestagen and ethynylestradiol was given during 21 days.

Instant claims differ from the reference in claiming a method of contraception where combination is broader in scope. Prior art teaches the treatment with gestagen first and than combination of estrogen and gestagen, it is presently claimed.

It would have been obvious to one skilled in the art to prepare additional contraceptive compositions by using gestagen in the first phase and then combination of estrogen and gestagen in the second phase because prior art teaches similar combination.

Three silastic rods impregnated with d-norgestrel each containing 40 mg of gestagen were inserted s.c. in the left forearm of 4 women for 100-458 days. After about 100 days 50mu.g of ethynylestradiol was given to 3 of the participants during 21 days. The amount of gestagen used during treatment suggests a contraceptive efficacy of at least two years. Motivation is provided by the prior art for the reasons cited above.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

In order to advance the prosecution Examiner called on 1/20/04 to speak to attorney Brion P. Heaney regarding possible amendments in claims. Examiner left the message; unfortunately no return call was received.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on every business day..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Sabiha N. Qazi
Primary Examiner
Art Unit 1616

1/24/04